

REMARKS

Amendments

Claim 5 is amended to be in independent form. Claim 19, although presently withdrawn, is amended to correct obvious typographical errors, i.e., replace the dash between 3 and 24 with a comma. New claims 36-42 are dependent on claim 5 and each recite subgroups of the compounds recited in claim 5. New claims 43-45 are recite specific definitions of groups Q and Z. See, e.g., page 7, lines 1-14, page 8, lines 13-16, and the exemplified compounds at pages 9-20. New claim 46 is similar to claim 1, except the proviso clause also excludes -CHOH- in which the OH group is esterified. See, e.g., page 5, lines 15-19 and page 7, lines 4-5. New claims 47 and 48 recite specific definition of groups Q consistent with the proviso clause of claim 46. See, e.g., page 7, lines 1-14.

Restriction

The Examiner has withdrawn the method of use claims 8-11 and 15-18. Applicants respectfully submit that this action is in violation of PCT Rule 13. As discussed in the ANNEX B of the PCT, Rule 13 is to be construed as permitting the inclusion in the same application claims directed to products, method of making, and method of use.

Also, there is no rationale basis for withdrawing compound claim 19 from consideration. There is no requirement that the claim be dependent, rather than independent. Further, it is noted that the compounds of claim 19 are 1,3,24-triol compounds which are not 24a-homh or 24a,24b-dihomo compounds.

Examination of claims 8-11 and 15-19 together with the other pending claims is respectfully requested.

Rejection Under 35 U.S.C. §103 In View of Kirsch et al. (WO '242)

Claims 1-3, 5, 6, 14, and 20 - 35 are rejected as being obvious under 35 USC §103 in view of Kirsch et al (US 6,372,731). This rejection is respectfully traversed.

In the rejection, reference is made to compounds 6a, 6b, 7b, and 8b of Figure 1; compounds 9b and 15b of Figure 2; compounds 16b and 18b of Figure 3; compound 27a and 28b in Figure 5; compounds 33a-43a in Figure 6; compounds 55a-70a and 55b-70b in Figure 8; and compounds 116b and 117b. These compounds each exhibit a side chain, attached to the C17 carbon atom, of the type -CH₂-CH(CH₃)-CH=CH-CH(OH)-cyclopropyl-R wherein

the C25, C26 and C27 carbon atoms form a cyclopropyl group and the C25 carbon atom is substituted by R, e.g. acetyl or 1-oxoalkyl.

These compounds exhibit the structure -CH(OH)- between the C23 and C25 carbon atoms and do not fall within applicants' claimed genus. However, the Examiner alleges that these compounds are homologues of compounds of applicants' claimed genus in which Q is -CH(OH)-CH₂- or is -CH(OH)-CH₂-CH₂-.

Firstly, this argument of homology, which is the only asserted reason for the rejection, presents no rationale for rejecting applicants' claims wherein Q is not -CH₂-CH(OH)- or -CH₂-CH₂-CH(OH)-. See, e.g., claims 30 and 43. Nor does it provide rationale for rejecting claims wherein the compounds differ from those compounds mentioned in the rejection by more than then a CH₂ or CH₂CH₂ group. See, e.g. claims 31-34.

Furthermore, the rejection presents no evidence to support the assertion that one of ordinary skill in the art would consider applicants' compounds and the specified compounds disclosed in US '731 to be homologs, that is members of a homologous series. Alkanes, i.e., methane, ethane, propane, etc., are recognized as members of a homologues series. Even alkanols, i.e., methanol, ethanol, propanol, etc., might be consider to be members of a homologues series. But, the Examiner has presented no arguments/evidence to support a theory that one of ordinary skill in the art might consider the compounds of US '731, which are exceedingly more complex than alkanes or alkanols, and applicants' claimed compounds to be members of the same homologous series.

Referring to the compounds of US '731 cited in the rejection, the insertion of a -CH₂- or -CH₂CH₂- group increases the distance between, for example, the -CO- group of group Z and the remainder of the compound, including other functional groups such as OH groups. These factors do not suggest that the compounds would be recognized as being so similar in structure as to be members of a homologous series.

Compare, for example, *Ex parte Goonewardene et al.*, 160 USPA 287, 288 (POBA 1968) wherein the rejected claims were directed to bicyclo[2.2.1]-2-heptenes having a side-chain CH₂-O-CO-NR'R". In reversing the rejection, the Board stated the following:

However, we do not find the clear suggestion in Senkbeil which would lead one skilled in the art to select the methylene group found in this reference and insert it into the appropriate place in the compounds of Johnson or Johnson et al. in order to obtain a product the same or similar to that claim. We note that a similar issue was involved

in *Ex parte Biel*, 124 USPQ 109, and which concerned a methylene group. In that decision it was held that the doctrine of homology would not be extended to embrace compounds involving such a significant difference in structure.

In *Ex parte Biel*, the Board in reversing a rejection based on the theory of homology stated that:

...we are inclined to agree with the appellant that the nearest compound disclosed by this reference cannot properly regard as the homologue of either PIPTAL or CANTIL because the reference compound has an alkylene group between the piperidine ring and the ester function, whereas the claimed compounds have no such alkylene group, the piperidine group and the ester group being directly bonded.

In *Ex parte Henze*, 83 USPQ 167 (POBA 1948), the case cited by the Examiner, the claimed compound and the prior art compound were **not** considered to be homologues. The claimed compound had a methyl group in the same position where the prior art compound had a phenyl group.

In the other cases cited by the examiner, the compounds differed by one or two methyl groups, not a methylene group. In *Ex parte Fauque*, 121 USPA 425 (POBA 1954), the claimed compound differed from the prior art compound by the replacement of 2H atoms in each case by a methyl group. The compounds were held to be part of the same homologues series. In *Ex parte Henkel*, 130 USPQ 474 (POBA 1960), the compound 1-phenyl-3-methyl-4-hydroxypyrazole was rejected in view of 1-phenyl-4-hydroxypyrazole. The compounds, differing by a methyl group, were held to be homologues. In *In re Lohr et al.*, 137 USPQ 548 (CCPA 1963) the prior art and claimed compounds differed by two methyl groups at the 2 and 6 positions of a six member heterocyclic nucleolus. In a footnote, the Court recognized that the compounds were “not homologues within the classic aliphatic chain sense and are not adjacent homologues in the tradition sense.” However, the Court found that the compounds were structurally similar whether or not they were adjacent homologues.

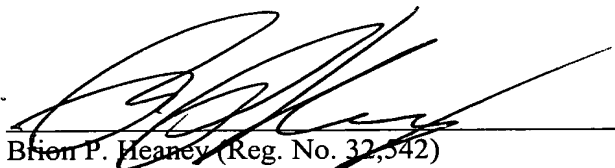
In *In re Druey et al.*, 138 USPQ 39 (CCPA 1963) the difference between the claimed 3-amino-2-phenyl-pyrazole compound and the prior art was a single methyl group. In finding the compound to be obvious, the Court indicated that it did not need to decide whether the

compounds were properly labeled homologues. In *In re Viechert*, 152 USPQ 247 (CCPA 1967), compounds within the claimed genus differed from the prior art compound by a single methyl group. In *In re Hoke* 190 USPQ 148 (CCPA 1977), the difference between the claimed polymers and the prior art polymers was the addition of two methyl groups. In *In re Wood* 190 USPQ 137 (CCPA 1978), the difference between the prior art compound and compounds falling within the claimed genus was a single methyl group. Finally, In *In re Magerlein*, 202 USPQ 473 (CCPA 1979), the difference between the prior art and the claimed compound was two methyl groups.

Thus, none of the cases cited by the Examiner provides any indication that the insertion of a methylene or ethylene group into the side chain of a complex compound would be considered to result in a homolog.

In view of the above remarks, it is respectfully submitted that US '731 fails to provide sufficient motivation to lead one of ordinary skill in the art to modify the compounds described therein in such a manner as to arrive at a compound according to applicants' claimed genus. Withdrawal of the rejection under 35 USC § 103 is respectfully requested.

Respectfully submitted,



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